REMARKS

The Official Action dated August 17, 2009 has been carefully considered. Accordingly, the present Amendment is believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claim 21 is amended to clarify that the method transfers a remedy to an external ophthalmic tissue in need of such a remedy and comprising at least one of conjunctiva, lacrimal tissue and cornea, and to specify that the remedy is for an ophthalmic disease of an external ophthalmic tissue selected from the group consisting of ocular infection in the external ophthalmic tissue comprising at least one of conjunctiva, lacrimal tissue and cornea, allergic conjunctivitis, pollinosis, vernal conjunctivitis, conjunctivitis, blepharitis, keratitis, corneal tumor, dacryocystitis, superficial keratitis, marginal blepharitis, scleritis, holdeolum, tarsadenitis, and trachoma. Support for these changes may be found throughout the specification, for example at page 6, lines 19-27, and page 20, lines 7-8, 11 and 15-17. Claim 2 is amended to limit the remedies to those encompassed by the remedies for an ophthalmic disease of the external ophthalmic tissue. Claim 23 is added, support for which may be found in the specification at page 45, line 19-page 46, line 2. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

In the Official Action, claim 2 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner asserted that drugs and classes of drugs recited in claim 2 are broader than what would be considered for the conditions in independent claim 21, namely ocular infection, allergic conjunctivitis, pollinosis and vernal conjunctivitis. As noted above, the remedies in claim 21 have been clarified and the agents of claim 2 have been limited to

correspond with the remedies of claim 21. Accordingly, claim 2 is believed to be definite and the rejection under 35 U.S.C. §112, second paragraph, is traversed with respect to claim 2 presented herein. Reconsideration is respectfully requested.

Claims 2-5, 8-15, 21 and 22 were rejected under 35 U.S.C. §102(b) as being anticipated by the Tojo et al PCT Publication WO 01/26648 and its corresponding U.S. Patent No. 7,052,714. The Examiner asserted that Tojo et al teach transdermal preparations comprising an adhesive with a drug, a release membrane and a lining film support and that the patch can be applied to any desired body surface including the eyelid. In response to Applicants' previous arguments, the Examiner asserted that that the application of the transdermal form of Tojo et al "inherently transfers the drugs through the skin and passes through the external portion of the eye to the internal portion of the eye" so the "components of the composition are delivered in the same manner as claimed." The Examiner also asserted that the application of the patch as taught in Tojo would inherently treat anyone who may have the conditions recited.

However, Applicants submit that the method of claim 21, and the methods of claims 2-5, 8-15 and 20 dependent thereon, are not anticipated by and are patentably distinguishable from Tojo et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, the present invention is directed to a method for transferring a remedy for ophthalmic disease to an external ophthalmic tissue in need of such a remedy and comprising at least one of conjunctiva, lacrimal tissue and cornea. The remedy is for an ophthalmic disease of the external ophthalmic tissue selected from the group consisting of ocular infection in the external ophthalmic tissue comprising at least one of conjunctiva, lacrimal tissue and cornea, allergic conjunctivitis, pollinosis, vernal conjunctivitis, conjunctivitis, blepharitis, keratitis, corneal tumor, dacryocystitis, superficial keratitis, marginal blepharitis, scleritis, holdeolum,

tarsadenitis, and trachoma. The method comprises applying a pressure-sensitive adhesive tape preparation comprising a plaster layer provided on a support, to a front skin surface of an upper eyelid and/or a lower eyelid to transfer the remedy for ophthalmic disease in the plaster layer to the external ophthalmic tissue by percutaneous permeation in such a manner that the remedy for ophthalmic disease is transferred by percutaneous permeation to the external ophthalmic tissue from the skin surface. The plaster layer contains the remedy for ophthalmic disease and a pressure-sensitive adhesive. The amount, in units of μg/g·tissue, of the remedy transferred by percutaneous permeation to the external ophthalmic tissue by the application within 8 hours after the application amounts to at least twice as much as the amount of the remedy transferred to the external ophthalmic tissue through a systemic blood flow.

The method of claim 21 differs from that of Tojo et al in at least four important respects, namely, the remedy for ophthalmic disease which is transferred, the target site to which the remedy is transferred, the method by which the remedy is predominantly transferred, and the unintended transfer to the non-targeted site. More specifically, Tojo et al is directed to an ophthalmic transdermal patch for treating diseases of the posterior segment of the eye, i.e., the lens, the vitreous body, the choroids and the retina (see, for example, column 1, lines 6-9). Tojo et al teach that their patch delivers drug to blood plasma which in turn delivers the drug to the posterior segment of the eye (see the in vivo test results at columns 12-13).

Thus, while Tojo et al teach transfer of a remedy for a disease of the posterior segment of the eye, the method of claim 21 is directed to a method for the transfer of a remedy for an ophthalmic disease of the external ophthalmic tissue, i.e., external ophthalmic tissue comprising at least one of conjunctiva, lacrimal tissue and cornea. Applicants find no teaching by Tojo et al of the transfer of a remedy for an ophthalmic disease of the external ophthalmic tissue, i.e.,

external ophthalmic tissue comprising at least one of conjunctiva, lacrimal tissue and cornea, other than by use of eye drops (see column 1, lines 16-20).

Second, Tojo et al's device targets the posterior segment of the eye, i.e., the lens, the vitreous body, the choroids and the retina. In contrast, the present method targets external ophthalmic tissue in need of a remedy for ophthalmic disease of the external ophthalmic tissue and comprising at least one of conjunctiva, lacrimal tissue and cornea. Applicants find no teaching by Tojo et al of the transfer of a remedy to an external ophthalmic tissue in need of a remedy for ophthalmic disease of the external ophthalmic tissue, i.e., external ophthalmic tissue comprising at least one of conjunctiva, lacrimal tissue and cornea, except, as noted above, by use of eye drops.

Third, according to Tojo et al, the remedy is transferred to the target site by percutaneous absorption, after which the drug is transferred into the blood to administer the drug to the posterior segment of the eye from the plasma in the blood through the systemic blood flow. For example, the Tojo et al test results examine both the plasma concentration and posterior eye concentration of active ingredient. Tojo et al indicate that the prednisolone amount was determined in the plasma and the eyeball of the rats to which were applied a 3% prednisolone-containing preparation, P5 and, as a result, 70 ng/g prednisolone was detected 6 hours after the application of the preparation, indicating that prednisolone was transferred to the interior of the eye at a concentration that was equivalent to 18% of the plasma concentration (Table 8, column 12, line 64-column 13, line 7). Additionally, Tojo et al disclose in Table 8 that 7.2 ng/g of SJA6017 was detected in the eyeball 12 hours after the application of the SJA6017-containing preparation, reaching about 16% of the plasma concentration of the drug, which is higher than the corresponding value (13%) detected after intravenous application. Tojo et al conclude that

this method of administration of a drug by transdermal patches is a method available to continuously transfer a drug from the plasma into the eyeball (column 13, lines 39-48).

In contrast, according to the method of claim 21, the predominate transfer of remedy to the target site is through percutaneous permeation, i.e., the amount, in units of μg/g·tissue, of the remedy transferred by percutaneous permeation to the external ophthalmic tissue by the application within 8 hours after the application amounts to at least twice as much as the amount of the remedy transferred to the external ophthalmic tissue through a systemic blood flow. In fact, in specific embodiments of the present invention, little or no drug is transferred from plasma to the target site of the external ophthalmic tissue. For example, as set forth in the present specification:

> "It is further apparent that the concentration of the drug in the conjunctivae of the other eye than the eye, to the eyelids of which the preparation has been applied is clearly lower than that in the eye patched, and that since the concentration of the drug in the plasma was lower than the detection limit value (< 0.005 μg/mL), the drug is percutaneously transferred to the conjunctivae from the eyelid parts, to which the preparation is applied, rather than the transfer to the conjunctivae through the systemic blood flow when the preparation is applied to the eyelid parts." (page 45, line 19-page 46, line 2).

> "Even from the experimental results shown in Table 6, it is apparent that the transfer of the drug to the anterior ocular segment (conjunctiva, lacrimal tissue, etc.) from the transdermal drug delivery system for treatment of ophthalmic diseases according to the present invention is conducted by percutaneous transfer from the applied site rather than the transfer through the systemic blood flow." (page 48, lines 14-21).

Thus, the predominate mechanism of transfer as claimed is significantly distinguishable from that of Tojo et al.

Finally, because the predominate mechanism of transfer of the agent in the method according to claim 21 is, as claimed, by percutaneous permeation, rather than systemic transfer from plasma, it is apparent that administration of the agent to body sites other than the diseased site are minimal according to the present methods. In contrast, in the method of Tojo et al, the systemic distribution of the agent to the target site of the posterior segment of the eye also

undesirably results in systemic distribution of the agent throughout the body. As it is an object of Tojo et al to increase drug concentration in the plasma and, as a result, systemic administration of the drug, such systemic administration which will occur in not only the desired target site of the posterior segment of the eye, but also other body areas, potentially causing unwanted side effects. This disadvantage is avoided by the present methods.

The Examiner asserted in the Official Action that the application of the transdermal form of Tojo et al inherently transfers the drugs through the skin and passes through the external portion of the eye to the internal portion of the eye so the components of the composition are delivered in the same manner as claimed. However, Tojo et al do not disclose any method for transferring a remedy for ophthalmic disease to an external ophthalmic tissue in need of such remedy other than by eye drops or subconjunctival injection (column 1, lines 16-20). The methods of Tojo et al which employ a pressure-sensitive adhesive tape preparation are for transferring a remedy for a different disease, namely one of the posterior segment of the eye, not a remedy for an external ophthalmic tissue disease and not to an external ophthalmic tissue in need of such a remedy. As shown in Table 1 in the present specification, the transdermal drug delivery method for treatment of ophthalmic diseases according to the present invention (Example 1) was recognized to have high transferability of ketotifen fumarate to the conjunctiva over a long period of time while, in contrast, it was demonstrated that an eye drop ophthalmic solution (Comparative Example 1) is rapidly washed out by tears, and only a small amount of the drug remains 1 hour after administration, and whereby potency over a long period of time cannot be expected (page 38, lines 9-18). The present methods therefore have a significant advantage over the use of eye drops, the method taught by Tojo et al as adequate for administering a remedy to an external ophthalmic tissue.

Additionally, while Tojo et al disclose that their preparations may be used to deliver drugs to the eye through the skin and other parts of the body and that the ophthalmic transdermal patches may be applied at any location of the body surface as desired, on a site relatively close to the eye, e.g., on the temple or around the eye, in particular on the skin of the eyelids or next to the lateral angle of the eye, the in-vivo examples of Tojo et al employ the patches on the abdominal skin (column 9, lines 11 and 45) and on "the skin of the animals" (column 12, lines 35-39). Moreover, since Tojo et al are concerned with systemic drug delivery, one of ordinary skill in the art would not expect the location of the Tojo et al patch to significantly effect the systemic drug delivery.

Further, while Tojo et al broadly refer to application to the eyelids, an example thereof is not provided and there is no recognition that application to an eyelid transfers a drug to external ophthalmic tissue in an amount of at least twice as much as is delivered systemically over an eight-hour period as recited in claim 21. In view of the failure of Tojo et al to exemplify application of a transdermal patch to an eyelid, particularly to transfer a remedy for an external ophthalmic disease to an external ophthalmic tissue in need of such a remedy, and in view of the unexpected and unpredictable increased drug transfer by percutaneous permeation as compared with systemic administration in the present method, the method of claim 21 is not inherent in the teachings of Tojo et al.

Moreover, a comparison test between a method according to the present invention wherein a preparation as claimed is applied to upper and lower eyelid parts and a method as exemplified in Tojo et al wherein a preparation is applied to the back is described in the present specification:

> "As apparent from the results shown in Table 4, it is understood that when the transdermal drug delivery system for treatment of ophthalmic diseases according to the

> present invention is applied to the skin of the back of the subject animal, the amount of the drug (ketotifen fumarate) penetrated into the skin surface under the application, absorbed in an intraepithelial blood capillary and reached the conjunctivae of both eyes through the systemic blood flow from the blood capillary is at the level of about 0.01 to 0.02 μg/g even when 4 hours, 8 hours and 24 hours have elapsed from the application, namely, the amount of the drug transferred to the ophthalmic topical tissues (conjunctivae of the external ophthalmic tissues) through the systemic blood flow is extremely little. On the contrary, it is understood that when the transdermal drug delivery system for treatment of ophthalmic diseases according to the present invention is applied to the skin surfaces of the upper and lower eyelids, the drug is transferred to the conjunctivae under the application at a concentration as high as 4.44 μg/g after 4 hours from the application, and the amount transferred retain high levels of 2.95 μg/g after 8 hours and 0.13 μg/g after 24 hours." (from page 43, line 17 to page 44, line 7).

Thus, the present methods of transferring a remedy to the external ophthalmic tissue including the conjunctiva, lacrimal tissue and cornea by percutaneous permeation have a significant advantage over the method exemplified by Tojo et al, and this advantage is neither recognized nor suggested by Tojo et al. The present methods have additional advantages as well. Efficacy of the remedy for ophthalmic disease is achieved faster as the percutaneous permeation delivers the remedy to the external ophthalmic tissue of the eye faster than it would be delivered through systemic blood flow. As a higher amount of the applied drug is delivered to the external ophthalmic tissue by percutaneous permeation as compared with delivery through systemic blood flow, even a drug low in percutaneous permeability can be administered in an amount sufficient to provide efficacy. Further, even when the remedy is a drug having skin irritability, efficacy and a reduction of skin irritability can be reconciled by controlling percutaneous absorbability and the amount permeating the skin. Finally, as noted above, problems with systemic drug delivery, including undesirable side effects, can be reduced or eliminated, and the efficacy of the remedy can be sustained over a long period of time. These advantages are demonstrated in the Examples in the present specification.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re*

Robertson, 169 F.3d 743 (Fed. Cir. 1999). As Tojo et al teach methods for treating diseases in the posterior segment of the eye by systemic blood flow delivery of a drug and teach that eye drops or subconjunctival injection techniques are adequate for drug delivery to the anterior segment of the eye, and Tojo et al do not teach a method for transferring a remedy for ophthalmic disease to an external ophthalmic tissue in need of such remedy and comprising at least one of conjunctiva, lacrimal tissue and cornea, Tojo et al do not describe each and every element of the present claim 21 and therefore do not anticipate claim 21. The rejection under 35 U.S.C. §102(b) is therefore overcome. Reconsideration is respectfully requested.

Claims 2-6, 8-15, 21 and 22 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Higo et al U.S. Patent No. 5,866,157 in view of the Trimming et al U.S. Patent Publication No. 2001/0006968, Tojo et al, and the Lerner et al PCT Publication WO 97/18855. The Examiner asserted that Higo et al teach the use of a transdermal patch which has increased percutaneous absorbability of the drug and reduced irritation to the skin, with a reservoir and a support, an absorption enhancer, a hydrophobic high molecular weight adhesive, a tackifying resin and other components. The Examiner admitted that Higo does not expressly teach an example with an acrylic polymer, but does teach the equivalence of the exemplified styrene-isoprene-styrene and polymers of acrylic acid. The Examiner relied on Trimming et al as teaching that ketotifen is useful for the treatment of allergic conjunctivitis, on Tojo et al as teaching that transdermal patches for ophthalmic conditions can be applied to any body surface including the eyelid, and on Lerner as teaching that the skin of the eyelid has a resistance lower than that on the rest of the skin. The Examiner concluded therefore that it would have been obvious to apply the ketotifen patch on the eyelid.

However, Applicants submit that claims 2-6, 8-15, 21 and 22 are not rendered obvious over, and are patentably distinguishable from, the combination of Higo et al, Trimming et al, Tojo et al and Lerner et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, as discussed in detail above, the present invention is directed to a method for transferring a remedy for ophthalmic disease to an external ophthalmic tissue in need of such a remedy and comprising at least one of conjunctiva, lacrimal tissue and cornea, wherein the remedy is for an ophthalmic disease of the external ophthalmic tissue selected from a defined group. The method comprises applying a pressure-sensitive adhesive tape preparation comprising a plaster layer provided on a support, to a front skin surface of an upper eyelid and/or a lower eyelid to transfer the remedy for ophthalmic disease in the plaster layer to the external ophthalmic tissue by percutaneous permeation in such a manner that the remedy for ophthalmic disease is transferred by percutaneous permeation to the external ophthalmic tissue from the skin surface. The plaster layer contains the remedy for ophthalmic disease and a pressure-sensitive adhesive. The amount, in units of μg/g·tissue, of the remedy transferred by percutaneous permeation to the external ophthalmic tissue by the application within 8 hours after the application amounts to at least twice as much as the amount of the remedy transferred to the external ophthalmic tissue through a systemic blood flow.

Higo et al disclose matrix type patch formulations which allow the physiological active substance to be absorbed via skin continuously into the circulating blood (column 6, lines 29-31). Test example 1 at column 16 applies patches to thawed human abdominal skin while Test example 2 at column 17 applies patches to normal human skin in the back region. Applicants find no teaching by Higo et al relating to transferring a remedy for ophthalmic disease selected

from the group recited in claim 21, particularly by applying a patch to a front skin surface of an upper eyelid and/or lower eyelid as presently claimed. Moreover, as Higo et al is concerned with delivering an active to blood, the improvements of the present invention in delivering the remedy to the external ophthalmic tissue in need of such a remedy in a greater amount according to the present invention is neither recognized nor predictable in view of Higo et al. Specifically, Higo et al provide no teaching, suggestion or recognition that the amount, in units of μg/g·tissue, of the remedy transferred by percutaneous permeation to the external ophthalmic tissue by the application within 8 hours after the application according to the present method amounts to at least twice as much as the amount of the remedy transferred to the external ophthalmic tissue through a systemic blood flow.

The deficiencies of Higo et al are not resolved by Trimming et al, Tojo et al or Lerner et al. That is, Trimming et al teach an ophthalmic composition, for example, eye drops, comprising ketotifen for treatment of allergic conjunctivitis is compatible with soft contact lens (paragraph [0003]). Thus, while Higo et al are directed to systemic administration compositions, Trimming et al are directed to eye drops. One of ordinary skill in the art would have no reason to combine any of the systemic administration composition teachings of Higo et al with the eye drops of Trimming et al as these two references relate to different administration routes and mechanisms and neither reference teaches, suggests or recognizes that application of a pressure-sensitive adhesive tape preparation to a front skin surface of an upper eyelid and/or a lower eyelid as presently claimed transfers a remedy for ophthalmic disease to an external ophthalmic tissue by percutaneous permeation.

Tojo et al, as discussed above, discloses devices for transferring a remedy to plasma for systemic delivery to the posterior segment of the eye. While Tojo et al disclose that their

preparations may be used to deliver drugs to the eye through the skin and other parts of the body and that the ophthalmic transdermal patches may be applied at any location of the body surface as desired, on a site relatively close to the eye, e.g., on the temple or around the eye, in particular on the skin of the eyelids or next to the lateral angle of the eye, the in-vivo examples of Tojo et al, like Higo et al, employ the patches on the abdominal skin (column 9, lines 11 and 45) and on "the skin of the animals" (column 12, lines 35-39). Moreover, since Tojo et al are concerned with systemic drug delivery, one of ordinary skill in the art would not expect the location of the Tojo et al patch to significantly effect the systemic drug delivery. Thus, Tojo et al, like Higo et al, fail to recognize that application to an eyelid transfers a remedy to external ophthalmic tissue in need of such a remedy in an amount of at least twice as much as is delivered systemically over an eight-hour period as recited in claim 21. To the contrary, Tojo et al indicate that eye drops are satisfactory for treating external ophthalmic conditions. In view of the failure of Tojo et al to exemplify application of a transdermal patch to an eyelid, particularly to transfer a remedy for an external ophthalmic disease to an external ophthalmic tissue in need of such a remedy, and in view of the unexpected and unpredictable increased drug transfer by percutaneous permeation as compared with eye drops and systemic administration, the method of claim 21 is not suggested by the teachings of Tojo et al.

Finally, Lerner et al disclose an iontophoresis device for enhancing the delivery of a drug into a selected organ or tissue, for example the brain, which device includes special electrodes connected with a selected energy source which maintains an energy field before and during the delivery of the drug. Beginning at page 37, line 34, Lerner et al disclose an embodiment for intracerebral transocularis wherein iontophoresis is conducted through the eyeballs. As noted by the Examiner, Lerner et al disclose that skin of the eyelid has a resistance lower than that on the

rest of the skin surface and a resistance of the cornea and of the sclera is negligible. It is apparent that Lerner et al are referring to resistance to the flow of current, as Lerner et al further indicate that in this method, a split active electrode must be placed over the eyes and is covered by cotton or other material wetted in the solution of the necessary active substance and touching the skin as the electrodes themselves must not touch the skin, another split electrode covered by cotton or other material and wetted in the water is fixed on the mastoid processors or on another place or a single passive electrode is fixed on the back of the head in the area of cervical vertebrae or on another place, and, depending on individual tolerance (pressure or some other unpleasant feelings), current intensity can increase up to 10 mA (page 38, lines 2-18).

Thus, Lerner et al are concerned with administration of a drug to the brain by bypassing the blood-brain barrier using iontophoresis. One of ordinary skill in the art would have had no apparent reason to combine any of the teachings of Lerner et al with either the systemic administration compositions of Higo et al or Tojo et al, or the eye drops of Trimming et al. Lerner et al's teaching of the resistance of the eyelids to the flow of current is simply irrelevant to the systemic administration of Higo et al and Tojo et al and to Trimming et al's eye drops.

In determining patentability under 35 U.S.C. §103, it is necessary to determine whether there was an apparent reason to combine the known elements of the prior art in the fashion of the claims at issue, *KSR International Co. v. Teleflex, Inc.*, 550 US 398, 418 (2007). Neither Higo et al nor Tojo et al teach a method for transferring a remedy for ophthalmic disease to an external ophthalmic tissue in need of such a remedy. Additionally, as Trimming et al and Lerner et al are directed to different and distinct modes of administration of actives, and none of these references provide any teaching of a method for transferring a remedy to an external ophthalmic tissue by percutaneous permeation to the external ophthalmic tissue in need of such a remedy, these

references cannot be properly combined to result in the method of claim 21. Accordingly, combination of these references does not render the method of claim 21 obvious, and the rejection under 35 U.S.C. §103 is therefore overcome. Reconsideration is respectfully requested.

Finally, claims 2-5, 8-15, 21 and 22 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 3-7, 11, 23 and 25-27 of copending application Serial No. 10/569,772 in view of Tojo et al. This rejection is traversed and reconsideration is respectfully requested.

Claim 21 is directed to a method for transferring a remedy for ophthalmic disease to an external ophthalmic tissue in need of such a remedy and comprising at least one of conjunctiva, lacrimal tissue and cornea, wherein the remedy is for an ophthalmic disease of the external ophthalmic tissue selected from a defined group of ocular infection in the external ophthalmic tissue comprising at least one of conjunctiva, lacrimal tissue and cornea, allergic conjunctivitis, pollinosis, vernal conjunctivitis, conjunctivitis, blepharitis, keratitis, corneal tumor, dacryocystitis, superficial keratitis, marginal blepharitis, scleritis, holdeolum, tarsadenitis, and trachoma. The claims of copending application Serial No. 10/569,772 are directed to methods of promoting lacrimal fluid secretion. Applicants submit that the copending application methods of promoting lacrimal fluid secretion are distinct and nonobvious over methods of transferring a remedy for ocular infection in the external ophthalmic tissue comprising at least one of conjunctiva, lacrimal tissue and cornea, allergic conjunctivitis, pollinosis, vernal conjunctivitis, conjunctivitis, blepharitis, keratitis, corneal tumor, dacryocystitis, superficial keratitis, marginal blepharitis, scleritis, holdeolum, tarsadenitis, and trachoma. The respective claims are therefore directed to distinct therapies, whereby the rejection should be withdrawn. Reconsideration is respectfully requested. Moreover, in the event that the provisional double patenting rejection is

the only rejection remaining in the present application, the rejection should be withdrawn in the present application, thereby permitting the present application to issue as a patent, MPEP §804.

It is believed that the above represents a complete response to Official Action, and places the present application in condition for allowance. In the event there are any outstanding issues relating to this application, the Examiner is urged to telephone the undersigned to efficiently resolve the same. Reconsideration and an early allowance are requested.

Please charge any fees required in connection with the present communication, or credit any overpayment, to Deposit Account No. 503915.

Respectfully submitted,

/Holly D. Kozlowski/
Holly D. Kozlowski, Reg. No. 30,468
Porter, Wright, Morris & Arthur LLP
250 East Fifth Street, Suite 2200
Cincinnati, Ohio 45202
(513) 369-4224